UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,259	11/06/2006	Edwin Pei Yong Chow	6565-76130-01	2433

24197 7590 05/20/2011

KLARQUIST SPARKMAN, LLP
121 SW SALMON STREET
SUITE 1600
PORTLAND, OR 97204

EXAMINER	
BECKHARDT, LYNDSEY MARIE	
ART UNIT	PAPER NUMBER
1613	

NOTIFICATION DATE	DELIVERY MODE
05/20/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

tanya.harding@klarquist.com
docketing@klarquist.com

Office Action Summary	Application No.	Applicant(s)	
	10/585,259	CHOW ET AL.	
	Examiner	Art Unit	
	LYNDSEY BECKHARDT	1613	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *16-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/17/2011, 11/11/2010, 09/10/2010, 06/03/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-24 are currently pending. Claims 1-15 are currently under examination.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/16/2010 has been entered.

Information Disclosure Statement

Applicant's Informational Disclosure Statement, filed on 06/03/2010, 09/10/2010, 11/11/2010, 02/17/2011 has been considered. Please refer to Applicant's copy of the 1449 submitted herein.

Examiner's Note

Unless otherwise indicated, previous objection/rejections that have been rendered moot in view of the amendment will not be reiterated. The arguments in the 03/16/2010 response will be addressed to the extent they apply to current rejection(s).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Rejections:

The following rejections are newly applied.

Claim Rejections - 35 USC § 103

Claims 1-7 and 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu (previously applied) in view of US 6,015,609, Vandamme (previously applied) and US 5,670,557.

Determining the scope and contents of the prior art.

Regarding claim 1, the Liu teaches a method of forming polymer comprising polymerizing a bicontinuous microemulsion (abstract) comprising a first continuous phase comprising water and a second continuous phase comprising a monomer (abstract, Figure 1) and a surfactant copolymerizable with said monomer to form a porous polymer (abstract) comprising a matrix portion formed from said second phase and comprising a polymer matrix and a water portion formed from said first phase and comprising water in interconnected pores defined by said matrix portion (page 6424, first column, first paragraph).

Regarding claim 3, Liu teaches wherein said pores have a pore diameter of about 10 to about 100 nm (abstract).

Regarding claim 4, Liu teaches wherein the proportion of said water is from 15% to about 50%, monomers is from about 5% to about 40% and surfactant (macromer) is from about 10% to about 50% (Table 1).

Regarding claims 5-6, Liu teaches wherein said microemulsion further comprises a cross-linker wherein the cross-linker is EGDMA (abstract).

Regarding claim 7, Liu teaches wherein said microemulsion further comprises a polymerization initiator (page 6422, first column, second paragraph).

Regarding claims 11-12, Liu teaches wherein said monomer is ethylenically unsaturated, wherein said monomer is MMA, HEMA or a combination thereof (abstract).

Regarding claims 13-15, Liu teaches wherein said surfactant is a nonionic surfactant, wherein said surfactant is polyethyleneoxide-macromer, C_1-PEO-C_{11}-MA-40 (abstract).

Liu does not teach wherein said micro emulsion further comprise a drug dispersed in at least said second phase, such that when said porous polymer is formed, said drug is initially dispersed in at least said matrix portion and is releasable from said matrix portion into said pores when said porous polymer is in contact with a liquid (claim 1).

Liu does not teach an ophthalmic drug (claim 2).

Regarding claim 1, the '557 patent teaches a microemulsion further comprises a drug dispersed (column 4, 60-65, column 31, lines 10-16), such that when said porous polymer is formed the drug is initially dispersed in at least said matrix portion (column 31, line 60 to column 32, lines 5).

Neither Liu nor the '557 patent teach an ophthalmic drug (claim 2).

Regarding claim 2, Vandamme teaches an ophthalmic drug (abstract, page 16, 1.1).

Regarding the limitation, ‘and is releasable form said matrix portion into said pores when said porous polymer is in contact with a liquid' is a functional limitation. The combination of references teach the claimed structure, e.g. monomers, surfactants made by polymerizing a bicontinuous structure containing an ophthalmic drug, and thus would be capable of the release as claimed, absent factual evidence to the contrary.

Ascertaining the differences between the prior art and the claims at issue, and Resolving the level of ordinary skill in the pertinent art.

People of the ordinary skill in the art will be highly educated individuals such as medical doctors, scientists, or engineers possessing advanced degrees, including M.D.'s and Ph.D.'s. Thus, these people most likely will be knowledgeable and well-read in the relevant literature and have the practical experience in methods of forming polymer for drug release. Therefore, the level of ordinary skill in this art is high.

"A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1397 (2007). "[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id.* Office personnel may also take into account "the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at ___, 82 USPQ2d at 1396.

Considering objective evidence present in the application indicating obviousness or nonobviousness.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the polymer taught by Liu for drug delivery as Liu is directed to a bicontinuous polymer structure having a porous structure (abstract) and the '609 patent teaches use of a bicontinuous polymer structure containing pores for an ophthalmic device and for drug delivery (abstract, column 10, lines 45-50, column 14, lines 15-21 and column 15, lines 5-10). One of ordinary skill in the art at the time the invention was made would have a reasonable expectation of success as Liu and the '609 patent are directed to bicontinuous (co-continuous) micro emulsions which are polymerized to form a porous structure (Liu: abstract; '609: abstract, column 10, lines 45-50) which contain overlapping monomers such as HEMA, acrylate monomers and EGDMA (Liu: abstract; '609: column 13, lines 43, column 9, lines 5-10, column 9, lines 33-35). One of ordinary skill in the art at the time the invention was made would have a reasonable expectation of success in using the polymer structure taught by Liu (abstract) for an ophthalmic device taught by the '609 patent (column 15, lines 5-10) because Liu teaches the polymer structures are transparent (abstract).

It would have been prima facie obvious to one of ordinary skill in the art to use the ophthalmic device taught by the '609 patent comprising the polymer structure taught by Liu for ophthalmic drug delivery because the '609 patent teaches the porous polymer structure can be used for sustained drug delivery (column 15, line 5) and Vandamme teaches the delivery of drugs through microemulsions containing ophthalmic drug with a

need to limit drainage of the drug and delay of drug delivery (abstract, page 16, first column, first paragraph). One of ordinary skill in the art at the time the invention was made would have a reasonable expectation of success as Vandamme, the '609 patent and Liu are all directed to bicontinuous emulsions.

It would have been obvious to one of ordinary skill to add the ophthalmic drug before polymerization of the microemulsion taught by Liu because the '557 patent teaches addition of an active agent before polymerization of a polymeric microemulsion structure (column 31, line 60 to column 32, line 4).

The cited prior art meets the criteria set forth in both *Graham* and *KSR*, and the teachings of the cited prior art provide the requisite teachings and motivations with a clear, reasonable expectation of success. Thus, absent evidence to the contrary, the invention as a whole is *prima facie* obvious.

Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu in view of US 6,015,609, Vandamme and US 5,670,557 as applied to claims 1-7 and 10-15 above, and further in view of Havermeyer et al. (previously applied).

As mentioned in the above 103(a) rejection, all the limitations of claims 1-7 and 10-15 are taught by the combination of Liu, the '609 patent, Vandamme and the '557 patent.

The combination of references does not teach DMPA (2,2-dimethoxy-2-phenylacetophenone) as the photoinitiator (claims 8-9).

Havermeyer teaches poly(methyl methacrylate) (PMMA) containing residual monomer and doped with the photoinitiator 2,2-dimethoxy-2-phenylacetophenone (DMPA) is a photosensitive system for light in the ultraviolet (UV) range. In illuminated regions DMPA molecules decay into free radicals and trigger polymerization reactions of the residual monomer. The light generated free radicals induce polymerization (page 201, first column, first paragraph).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made that DMPA taught by Havermeyer could be used for the polymerization initiator in the polymerization taught by Liu because Havermeyer teaches polymer of PMMA using DMPA as an initiator (page 201, first column, first paragraph) and Liu teaches the monomers in the polymerization include MMA (abstract).

Response to Arguments:

Applicant argues Vandamme teaches eye drops formed from micro emulsions, which are liquid. One of skill would not polymerize the microemulsion of Vandamme as the main advantage of the microemulsion is to increase the solubilization of the drugs, which would be destroyed by polymerizing the oil. Vandamme teaches away from delivery from a drug in a solid carrier.

In response, Vandamme further teaches an advantage being a delayed effect and limiting of the drainage of the drug (abstract). The ‘609 patent teaches sustained drug delivery from the porous polymer structure (column 15, line 5). One of skill in the art would be motivated to include the drugs of Vandamme in the polymer structure of Liu and the ‘609 patent in order to obtain sustained release of the ocular active agent.

Applicant argues there is no evidence in the cited references to support the assertion that a drug dispersed in the oil phase would inherently releasable after polymerization of the oil phase. It is difficult for the drug to release from a matrix portion formed form a monomer phase. A skilled person would expect that the drug would be trapped or boded in the polymer matrix.

In response, the '557 patent teaches addition of an active agent before polymerization of a polymeric microemulsion structure to form a drug delivery device (column 31, line 60 to column 32, line 4). Thus the skilled artisan would be aware that inclusion of a drug during microemulsion polymerization is a viable method for making a drug delivery device.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYNDSEY BECKHARDT whose telephone number is (571)270-7676. The examiner can normally be reached on Monday thru Thursday 7:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Kwon can be reached on (571) 272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LYNDSEY BECKHARDT/
Examiner, Art Unit 1613

/Kevin K. Hill/
Primary Examiner, Art Unit 1633